See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 35-R-0030 CUSTOMER NUMBER: 640

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Covance Laboratories Inc 3301 Kinsman Boulevard Madison, WI 53704

Telephone:

(b)(2)High, (b)(7)f

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

| A.  | B. Number of animal   | C. Number of   | D. Number of animals upon  | E. Number of animals upon which teaching, experiments,  | F.   |
|---|---|--|--|---|--|
| Animals Covered<br>By The Animal<br>Welfare Regulations | being bred,<br>conditioned, or<br>held for use in<br>teaching, testing,<br>experiments,<br>research, or<br>surgery but not ye<br>used for such<br>purposes. | animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs. | which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquillz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report | TOTAL NUMBER<br>OF ANIMALS<br>( COLUMNS<br>C + D + E ) |
| 4. Dogs   | 431   | 5,009  | 924  | l l   | 5,934  |
| 5. Cats   | 0   | 0  | O  | 0   | 0  |
| 6. Guinea Pigs  | 6   | 180  | 46   | 0   | 226  |
| 7. Hamsters   | 14  | (1)  | 13   | 0   | 124  |
| 8. Rabbits  | 199   | 2,734  | 851  | 1.1   | 3,596  |
| 9. Non-human Primates                                   | 890   | 5,864  | 1,028  | 0   | 6,892  |
| 10. Sheep   | 0   | Ó  | 0  | 0   | ′ 0  |
| 11. Pigs  | 8   | 158  | 37   | 0   | 195  |
| 2. Other Farm Animals                                   | 0   | ٥  | 0  | 0   | 0  |
| 13. Other Animals                                       | 7   | 43   | 0  | 0   | 43   |
|   |   |  |  |   |  |

#### ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incident explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)

(B)(6) (B)(7)(c)

DATE SIGNED 11 21 208

( AUG 91 )

# Category E Animals 10/1/07 – 9/30/08

NOTE: All animals were used on (b)(4) and the pain/distress resulted from test article exposure or research procedures (e.g., oral gavage). The pain/distress could not be relieved due to rapid onset of signs or lack of obvious clinical signs prior to death, in most of these circumstances.

### (1) Rabbits:

## 4 Animals - Category E

Four rabbits had two or more consecutive days of low food consumption with concomitant decreases in body weight. Clinical observations for animals included, few/no feces, brown hair coat, and liquid feces. Clinical observations for two of the four animals included pale appearance, hypoactive, brown hair coat, liquid feces, soft feces, few/no feces labored respiration, and recumbent posture. All animals were found dead.

Laboratory communication error resulted in condition not being reported to the study director or veterinarian.

#### (2) Dog:

#### 1 Animal - Category E

A 10 mg/kg/day male was found dead during post dose observations on Day 20. Clinical signs of foamy vomit in cage, evidence of epistaxis, and blood in the oral cavity were consistent with accidental aspiration.

#### (3) Rabbit:

#### 2 Animals - Category E

One Group 2 rabbit found dead immediately after dosing on GD 7 and replaced. One Group 3 rabbit found dead immediately after dosing on GD 13. Both rabbits had evidence for dosing error (immediate signs of labored respiration, hypo activity and/or fluid-filled thoracic cavity at necropsy).

# (4) Rabbit:

# 5 Animals - Category E

Five animals were found dead in the a.m. (were normal at last check [p.m.]) and their status prior to death can not be determined. One rabbit struggled and jumped out of the restraining device with the gavage tube inserted. This animal died before any action could be taken.